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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,014	07/25/2003	Anthony H. Cincotta	102392-200	3686

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WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
03/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,014	CINCOTTA, ANTHONY H.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed December 3, 2007 have been received and entered into the application.

Action Summary

The rejection of claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over Connor (U.S.Patent No. 6,686,337 B2) and Cincotta et al. (U.S.Patent No. 5,741,503) is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicant's arguments filed December 3, 2007 have been fully considered but they are not persuasive. Applicant argues that the new and novel point of the invention is the discovery that patients suffering from metabolic syndrome or Type 2 diabetes may be treated by increasing the central dopaminergic neuronal activity novel while simultaneously decreasing the central noradrenergic neuronal activity level as disclosed and particularly claimed in the claim 2. Moreover, this simultaneous treatment results in an increase in the ratio of dopaminergic neuronal to noradrenergic neuronal activity within the hypothalamus of the central nervous system of the patient as disclosed and particulary claimed in claim 1. This is not found persuasive because each of the claimed mechanism set forth in claims are well known individually as useful

mechanisms in the treatment of metabolic syndrome such as obesity. It is noted that Connor teaches that apomorphine is an appetite-suppressant agent acting through dopamine mechanism while fusaric acid is useful for treating obesity. Therefore, Applicant's claimed mechanisms in a combination is individually achieved by the employment of the each of the agents taught by the prior art.

As stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Therefore, it would have been prima facie obvious to combine apomorphine and fusaric acid composition conjointly in a formulation to treat obesity. That applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological affects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connor (U.S.Patent No. 6,686,337 B2) of record and Cincotta et al. (U.S.Patent No. 5,741,503) of record.

Connor teaches that apomorphine is an appetite-suppressant agent acting through dopamine mechanisms. (column 3, lines 15-18, column 6, lines 53-60).

Cincotta et al. teaches that fusaric acid is useful for treating metabolism disorder such as obesity. Cincotta et al. teaches the effective amounts of fusaric acid for the treatment is from about 1 to about 150 mg/kg of body weight per day. (column 1 lines 10-24, column 5, lines 25-32, column 7, lines 10-27).

The claims differ from the cited references in claiming combination of apomorphine and fusaric acid, to treat metabolic disorder such as obesity and the mechanism of action of increasing the ratio of dopaminergic neuronal to noradrenergic neuronal activity within the hypothalamus of the central nervous system and the amount ratio.

To employ combinations of apomorphine and fusaric acid to treat metabolic disorders such as obesity would have been obvious because all the components are well known individually for treating obesity. It would be expected that the combination of components would treat obese conditions as well. The motivation for combining the

components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). The mechanism of action by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects individually which would result from the claimed obvious method, because the compound and its property is inseparable. Further, the amount ratio of active agents to be used in the known therapy is well within one of ordinary skill in the art because the amount ratio of active agent can vary depend on the orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe case of a disorder would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
February 21, 2008